

## **REMARKS**

### **Status of the Claims**

Upon entry of the present amendment, claims 5-6 and 27-32 will be pending in the present application. Claims 1-4, 7-26, and 33 have been cancelled herein. Claims 5, 27, and 28 have been amended. Claim 5 has been rewritten into independent form, and claims 27 and 28 were amended to depend from claim 5. No new matter has been inserted.

### **Issues under 35 U.S.C. § 102(b)**

1) Claims 1-4 have been rejected under 35 U.S.C. § 102(b) as being anticipated by Webster et al. '981 (U.S. 3,332,981).

2) Claims 1-2 have been rejected under 35 U.S.C. § 102(b) as being anticipated by Nagai et al. '675 (U.S. 5,665,675).

3) Claims 1-2 have been rejected under 35 U.S.C. § 102(b) as being anticipated by Minami et al. '094 (U.S. 5,710,094).

4) Claims 1-2 have been rejected under 35 U.S.C. § 102(b) as being anticipated by Nagai et al. '369 (U.S. 5,811,369).

5) Claims 1-2 have been rejected under 35 U.S.C. § 102(b) as being anticipated by Fukuchi et al. '368 (U.S. 5,811,368).

Claims 1-4 have been cancelled herein, which renders the rejections as to these claims moot. Thus, Applicants respectfully request that the rejections be withdrawn.

### **Issue under 35 U.S.C. § 112, first paragraph**

The Examiner has rejected claim 27 under 35 U.S.C. § 112, first paragraph, as failing to comply with the written description requirement. Specifically, the Examiner states that the term "therapeutically effective amount" of the compounds is not defined in the specification. Applicants respectfully traverse.

The specification clearly defines the term "therapeutically effective amount" at, *inter alia*, page 19, lines 13-24 and page 20, lines 1-6. These passages are reiterated below for the Examiner's convenience.

Page 19:

The actual dosage depend on the nature and severity of the disease being treated, and is within the discretion of the physician, and may be varied by titration of  
15 the dosage to the particular circumstances of this invention to produce the desired therapeutic effect. However, it is presently contemplated that pharmaceutical compositions containing of from about 0.1 to about 500 mg of active ingredient per individual dose, preferably of from about 1 to about 100 mg, most preferred of from about 1 to about 10 mg, are suitable for therapeutic treatments.

20 The active ingredient may be administered in one or several doses per day. A satisfactory result can, in certain instances, be obtained at a dosage as low as 0.1 µg/kg i.v. and 1 µg/kg p.o. The upper limit of the dosage range is presently considered to be about 10 mg/kg i.v. and 100 mg/kg p.o. Preferred ranges are from about 0.1 µg/kg to about 10 mg/kg/day i.v., and from about 1 µg/kg to about 100 mg/kg/day p.o.  
25

Page 20:

It is at present contemplated that suitable dosage ranges are 0.1 to 1000 milligrams daily, 10-500 milligrams daily, and especially 30-100 milligrams daily, dependent as usual upon the exact mode of administration, form in which administered, the indication toward which the administration is directed, the subject  
5 involved and the body weight of the subject involved, and further the preference and experience of the physician or veterinarian in charge.

Thus, Applicants respectfully submit that claim 27 does comply with the written description requirement and request that the rejection be withdrawn.

As the above amendments and remarks address and overcome the rejections, withdrawal thereof and allowance of the claims are respectfully requested. Applicants note that claims 5 and 6 were objected to, presumably due to their dependency on a rejected base claim. Claim 5 has been rewritten into independent form with claim 6 dependent thereon. Thus, Applicants respectfully submit that claims 5 and 6 are allowable.

**Request for Rejoinder**

Rejoinder is explained in MPEP § 821.04 as follows. Where product and process claims drawn to independent and distinct inventions are presented in the same application, applicant may be called upon under 35 U.S.C. § 121 to elect claims to either the product or process. See MPEP § 806.05(f) or § 806.05(h). The claims to the nonelected invention will be withdrawn from further consideration under 37 C.F.R. § 1.142. See MPEP § 809.02(c) and § 821 through 821.03. However, if applicant elects claims directed to the product and a product claim is subsequently found allowable, withdrawn process claims which depend from or otherwise include all the limitations of the allowable product claim will be rejoined.

As stated above, Applicants respectfully submit that claim 5 is allowable. As such, Applicants respectfully request the rejoinder of withdrawn claims 28-32, which ultimately depend from claim 5.


**CONCLUSION**

Should there be any outstanding matters that need to be resolved in the present application, the Examiner is respectfully requested to contact MaryAnne Armstrong, Ph.D., Registration No 40,069, at the telephone number of the undersigned below, to conduct an interview in an effort to expedite prosecution in connection with the present application.

If necessary, the Commissioner is hereby authorized in this, concurrent, and future replies, to charge payment or credit any overpayment to our Deposit Account No. 02-2448 for any additional fees required under 37 C.F.R. § 1.16 or under § 1.17; particularly, extension of time fees.

Dated: **APR 2 8 2008**

Respectfully submitted,

By  #42.874  
MaryAnne Armstrong, Ph.D.  
Registration No.: 40,069  
BIRCH, STEWART, KOLASCH & BIRCH, LLP  
8110 Gatehouse Road  
Suite 100 East  
P.O. Box 747  
Falls Church, Virginia 22040-0747  
(703) 205-8000  
Attorney for Applicants